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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/501,606	04/11/2005	Michael Vajdy	PP18892.003	9598

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EXAMINER

STUCKER, JEFFREY J

ART UNIT PAPER NUMBER

1648

DATE MAILED: 10/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/501,606

Applicant(s)

VAJDY ET AL.

Examiner

Jeffrey Stucker

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) 3 and 17-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 4-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 9/13/05.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

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Restriction to one of the following inventions is required under 35 U.S.C. § 121:

Group 1, claims 1, 2, and 4-16, in part, drawn to a composition comprising an HIV envelope antigen and LTK63.

Group 2, claims 1 and 3-16, in part, drawn to a composition comprising an HIV envelope antigen and LTR72.

Group 3, claim 17, in part, drawn to a composition comprising nucleic encoding an HIV envelope antigen and LTK63.

Group 4, claim 17, in part, drawn to a composition comprising nucleic acid encoding an HIV envelope antigen and LTR72.

Group 5, claim 18, in part, drawn to a composition comprising an HIV envelope antigen and a nucleic acid that encodes LTK63.

Group 6, claim 18, in part, drawn to a composition comprising an HIV envelop antigen and a nucleic acid that encodes LTR72.

Group 7, claims 19-27, in part, drawn to a method of using a composition comprising an HIV envelope antigen and LTK63.

Group 8, claims 19-27, in part, drawn to a method of using a composition comprising an HIV envelope antigen and LTR72.

Group 9, claim 28, in part, drawn to a method of using a composition comprising nucleic encoding an HIV envelope antigen and LTK63.

Group 10, claim 28, drawn to a method of using a composition comprising nucleic acid encoding an HIV envelope antigen and LTR72.

Group 11, claim 29, in part, drawn to a method of using a composition comprising an HIV envelope antigen and a nucleic acid that encodes LTK63.

Group 12, claim 29, in part, drawn to a method of using a composition comprising an HIV envelop antigen and a nucleic acid that encodes LTR72.

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The inventions listed as Groups 1-12 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The technical feature of the invention, LTK63, is known in the art and cannot be said to be a special technical feature. See Partidos et al. (The adjuvant effect of a non-toxic mutant of heat-labile enterotoxin of *Escherichia coli* for the induction of measles virus-specific CTL responses after intranasal co-immunization with a synthetic peptide, *Immunology* 89:483-487 (1996), cited in the Search Report). See also, Vajdy et al. which teaches LTK63 as an adjuvant for HIV envelope, as discussed below. Therefore, the claims cannot be said to have unity of invention.

During a telephone conversation with Helen Lee on 9/23/05 a provisional election was made with traverse to prosecute the invention of Group I, claims 1, 2, and 4-16. Affirmation of this election must be made by applicant in replying to this Office action. Claims 3 and 17-29 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4-6, and 14-16 are rejected under 35 U.S.C. § 102(b) as being anticipated by Vajdy et al. (7th Conf. on Retroviruses and Opportunistic Infections, 2000).

The claimed invention is drawn to a composition suitable for mucosal administration comprising an HIV envelope antigen and LTK63. The composition is suitable for intranasal, intra-vaginal, and intra-rectal delivery.

Vajdy et al. teach that the mucosal adjuvant LTK63, in combination with an antigen, when applied to a mucosal surface, induces a systemic and mucosal immune response. This indicates that this composition is suitable for intranasal, intra-vaginal, and intra-rectal administration. The Ogp140 antigen is an

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optimized envelope antigen. Thus, the claimed invention is anticipated by Vajdy et al.

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103(a).

Claims 1, 2, 4-10 and 13-16 are rejected under 35 U.S.C. § 103(a) as obvious over by Vajdy et al. (7th Conf. on Retroviruses and Opportunistic Infections, 2000).

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The claimed invention is further limited to a second antigen wherein the second antigen is gag.

Vajdy et al. teach a composition comprising LTK63 and gag. The reference teaches that it is suitable for administration to mucosal surfaces and can induce an immune response. The reference teaches not only an envelope antigen as discussed above, but also a gag antigen. However, the two are apparently administered separately in this reference. It would have been obvious to one of ordinary skill in the art at the time the invention was made to administer both antigen in the same composition so as to induce a multivalent response with a single composition. One would be motivated to do this for the convenience of medical staff and their patients who would need to have one treatment instead of two to get the same result. Thus, the claimed invention is obvious over Vajdy et al.

Claims 1, 11, and 12 are rejected under 35 U.S.C. § 103(a) as obvious over by Vajdy et al. (7th Conf. on Retroviruses and Opportunistic Infections, 2000) in view of Spalding (IDS ref. C6).

Claims 11 and 12 are further limited as comprising an additional antigen wherein the additional antigen is tat or Vpu.

The relevance of Vajdy et al. is set forth above.

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Spalding teaches that several formulations for inducing immune responses are known in the art and some are patented. The reference specifically teaches tat and Vpu. See the table on the second page. It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine one or more of the known antigens with the LTK63 mucosal adjuvant. One would be motivated to do this for the advantages taught by Vajdy et al. such as inducing a systemic as well as mucosal immune response which would protect mucosa at the site of viral entry. Thus, the instant invention is obvious over by Vajdy et al. in view of Spalding.

No claims are allowed.

Papers related this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989).

The Group 1600 Official Fax number is: (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Tech Center representative whose telephone number is (571)-272-1600.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Stucker whose telephone number is (571)-272-0911. The examiner can normally be reached Monday to Thursday from 7:00am-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (571)-272-0902.



**JEFFREY STUCKER**  
**PRIMARY EXAMINER**